REMARKS

Claims 6-14 were pending in the application. Claims 11-14 have been cancelled as being drawn to a non-elected invention. Claims 7-9 have been amended. Claims 15-17 have been added. A "Version with Markings to Show Changes Made" is attached hereto as Appendix A. Accordingly, claims 6-10 and 15-17 will be pending upon entry of the amendment. For the Examiner's convenience, all of the pending claims are listed in Appendix B.

Support for the amendments can be found throughout the specification and claims as originally filed. For example, support for the amendment to claim 7 can be found in the specification at least at page 10, lines 1-5; support for the amendment of claim 8 can be found in the specification at least at page 10, line 16-20, and page 11, Table 1 condition A; support for the amendment of claim 9 can be found in the specification at least at page 9, line 18-23.

No new matter has been added by these amendments. Amendment or cancellation of the claims should in no way be construed as acquiescence to any of the Examiner's rejections and was done solely to expedite prosecution. Applicants reserve the right to pursue the claims as originally filed in this or a separate application(s).

Claim Rejections – 35 U.S.C. §§101 and 112

Claims 6-10 were rejected on the ground that the claimed invention is not supported by either a specific, substantial asserted utility or a well-established utility, and is therefore not enabled.

Applicants respectfully traverse the forgoing rejection for the following reasons. The PTO Guidelines for Examination of Applications for Compliance with the Utility Requirement indicate that the requirement for utility is met "(1) if a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention, and (2) the utility is specific, substantial and credible." (The Federal Register Vol. 66, No.4, January 5, 2001, page 1098, column 1). Applicants respectfully submit that a ***specific, substantial and credible utility*** for the claimed invention is immediately apparent from Applicants' specification and the knowledge in the art at the time of Applicants' invention.

At the time of Applicants' invention galectins were known to comprise a family of evolutionarily conserved proteins which bind glycoconjugates (e.g., lactose). Members of this family were known to be involved in a number of important biological processes that require

carbohydrate recognition including cell adhesion, cell growth regulation, inflammation, immunomodulation, apoptosis and metastasis. For example, U.S. Patent 6,027,916 (cited by the Examiner) describes (1) that galectin 1 was known to participate in cell proliferation, and to regulate the immune response mediating apoptosis of T cells; (2) that galectin 3 promotes the growth of cells, and confers resistance to apoptosis; and (3) that three additional galectins, identified by the inventors by homology to other galectins, were believed to be active in modulating cell growth regulatory activities, immunomodulatory activity, cell-cell and cell substrate interactions, and apoptosis (column, 1, line 50 to column 2, line 4; column 17, lines 36-43).

Applicants of the present invention discovered a novel member of the galectin family. The DNA encoding this protein was isolated from human stomach cancer cells, and the specification teaches that the amino acid sequence demonstrates a high level of homology to other galectin family members (page 13, line 13 to page 14, line 16). The specification also teaches that the claimed polypeptides have lactose-binding activity (page 16, line 21 to page19, line 14), and are expressed most strongly in the peripheral blood, with lower levels of expression also observed in the heart, placenta, lung, spleen, thymus, ovary, small intestine and large intestine (page 20, lines 1-5). Moreover, the specification further teaches assays for measuring the ability of the claimed polypeptides to modulate cell proliferation, immunomodulation, and inflammation.

Accordingly, Applicants asserted utility is ***specific and substantial***. The claimed polypeptides have been shown to have at least one ***specific*** activity, *i.e.*, binding of lactose. Furthermore, since regulation of cell proliferation, immunomodulation, and inflammation is a desirable outcome based upon a need in the art, the claimed polypeptides have an asserted utility that is ***substantial***.

In addition, Applicants' asserted utility is ***credible***. As stated in the Federal Register (Vol. 66, No. 4, page 1096):

> when a patent application claiming a nucleic acid asserts a specific, substantial and credible utility, and bases the assertion upon homology to existing nucleic acids or proteins having an accepted utility, the asserted utility *must be accepted* by the examiner unless the Office has sufficient evidence or sound scientific reasoning to rebut such an assertion. "[A] 'rigorous correlation' need not be shown in order to establish practical utility; 'reasonable correlation' is sufficient," *Fujikawa v. Wattanasin,* 93 F.3d 1559,

1565, 39 USPQ2d 1895, 1900 (Fed. Cir. 1996). The Office will take into account both the nature and degree of homology.

Based on the ample teachings in Applicants' specification as well as the state of the art at the time of Applicants' invention, one of ordinary skill in the art, would have concluded that Applicants' asserted specific and substantial utility to be ***credible.***

In view of the forgoing, it is evident that the claimed polypeptides meet the requirements of both utility and enablement, and reconsideration and withdrawal of these rejections under 35 U.S.C. §§101 and 112, first paragraph, are respectfully requested.

Claim Rejections - 35 U.S.C. § 112, Second Paragraph

Claims 7 and 8 were rejected as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention."

Applicants respectfully submit that the rejection of claims 7 and 8 has been obviated by the amendment of these claims. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

Claims rejections - 35 USC §102

Claims 1, 8 and 9 were rejected under 35 U.S.C. 102(a) as being anticipated by Tuereci et al (Journal of Biological Chemistry, March 1997, Vol. 272, pp. 6416-6422). Claim 1 has been cancelled. Claim 8 has been amended to specify that the claimed polypeptide must be a naturally occurring allelic variant of the polypeptide of SEQ ID NO:2, and be encoded by a nucleic acid that hybridizes under highly stringent conditions to the complement of the nucleic acid of SEQ ID NO:3. Claim 9 has been amended to specify that the claimed polypeptide is more than 90% identical to the amino acid sequence of SEQ ID NO:1 or 2. Accordingly, Applicants respectfully request that this rejection be reconsidered and withdrawn.

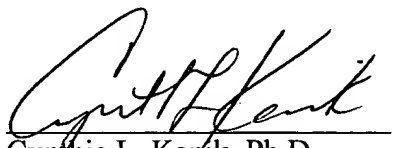
Claim 9 was also rejected under 35 U.S.C. 102(a) as being anticipated by Wada et al (Journal of Biological Chemistry, March 1997, Vol. 272, pp. 6078-6086), and under 35 U.S.C. 102(e) as being anticipated by Ni et al. (U.S. Patent 6,027,916). In view of the present amendment of claim 9 to specify that the claimed polypeptide is 90% identical to the amino acid sequence of SEQ ID NO:1 or 2, reconsideration and withdrawal of these rejections are requested.

CONCLUSION

In view of the foregoing, Applicants respectfully submit that the application is in condition for allowance, and such action is requested. If a telephone conversation with Applicants' attorney would expedite prosecution of the above-identified application, the Examiner is urged to call the undersigned at (617) 227-7400.

Respectfully submitted,

LAHIVE & COCKFIELD, LLP



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Dated: **February 27, 2002**

APPENDIX A

Version With Marking To Show Changes Made

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In the Claims:

Claims 11-14 were cancelled, claims 7-9 were amended, and claims 15-17 were added as follows.

7. **(Amended)** An isolated polypeptide consisting of a fragment of a polypeptide comprising the amino acid sequence of SEQ ID NO:~~1 or~~ 2, wherein the fragment comprises at least ~~88~~ 30 contiguous amino acids of SEQ ID NO:~~1 or~~ 2.

8. **(Amended)** A ~~An isolated polypeptide consisting of a~~ naturally occurring allelic variant of a polypeptide comprising the amino acid sequence of SEQ ID NO:~~1 or~~ 2, wherein the polypeptide is encoded by a nucleic acid molecule which hybridizes ~~to a nucleic acid molecule comprising SEQ ID NO:1 or 2 under stringent conditions~~. in 1X SSC at 65° C, followed by one or more washes in 0.3X SSC, at 65° C to a complement of a nucleic acid having the nucleotide sequence of SEQ ID NO:3.

9. **(Amended)** A polypeptide which is at least ~~70% homologous~~ 90% identical to a polypeptide ~~encoded by~~ comprising the amino acid sequence of SEQ ID NO:1 or 2.

15. **(New)** The isolated polypeptide of claim 6 further comprising heterologous amino acid sequences.

16. **(New)** The isolated polypeptide of claim 8 further comprising heterologous amino acid sequences.

17. **(New)** The isolated polypeptide of claim 9 further comprising heterologous amino acid sequences.

APPENDIX B

Pending Claims

6. An isolated polypeptide comprising the amino acid sequence of SEQ ID NO:1 or 2.

7. An isolated polypeptide consisting of a fragment of a polypeptide comprising the amino acid sequence of SEQ ID NO:2, wherein the fragment comprises at least 30 contiguous amino acids of SEQ ID NO:2.

8. A naturally occurring allelic variant of a polypeptide comprising the amino acid sequence of SEQ ID NO:2, wherein the polypeptide is encoded by a nucleic acid molecule which hybridizes in 1X SSC at 65° C, followed by one or more washes in 0.3X SSC, at 65° C to a complement of a nucleic acid having a nucleotide sequence of SEQ ID NO:3.

9. A polypeptide which is at least 90% identical to a polypeptide comprising the amino acid sequence of SEQ ID NO:1 or 2.

10. The isolated polypeptide of claim 7 further comprising heterologous amino acid sequences.

15. The isolated polypeptide of claim 6 further comprising heterologous amino acid sequences.

16. The isolated polypeptide of claim 8 further comprising heterologous amino acid sequences.

17. The isolated polypeptide of claim 9 further comprising heterologous amino acid sequences.